FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS PHARMA AG, and NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD., Plaintiffs, v. ROXANE LABORATORIES, INC. Defendant.	**Hon. Dennis M. Cavanaugh** **AMENDED OPINION** Civil Action No. 08-CV-3853 (DMC)(JAD)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon three motions for summary judgment by Novartis International Pharmaceutical Ltd. ("NIP"), Novartis Pharmaceutical Corporation ("NPC") and Novartis Pharma, AG ("NPAG") (collectively "Plaintiffs") and two motions for summary judgment by Defendant, Roxane Laboratories, Inc. ("Roxane") pursuant to Fed. R. Civ. P. 56. Plaintiffs also filed a cross motion to preclude Roxane's inequitable conduct contention and evidence, or alternatively, to strike those portions of Roxane's motion for summary judgment. Pursuant to Fed. R. Civ. P. 78, no oral argument was heard. After considering the submissions of the parties, the decision of this Court is set forth for the reasons expressed below.

I. BACKGROUND[1]

Plaintiffs market and sell the drug Famvir® in the United States for the treatment of various

[1] The facts set forth in this Opinion are taken from the Parties' statements in their respective moving papers.

herpes-related infections. The active antiviral agent in Famvir® is the chemical compound famciclovir. Plaintiffs' patent in suit, U.S. Patent No. 5,246,937 (the "'937 patent"), claims the compound famciclovir and its use for treating viral infections.

The '937 patent, entitled "Purine Derivatives," was issued on September 21, 1993 to Michael R. Harnden and Richard L. Jarvest, with Beecham Group PLC as the assignee.[2] The '937 patent claims priority to three British patent applications including GB 8423833 filed on September 20, 1984, GB 8510331 filed April 23, 1985 and GB 8520618 filed August 16, 1985. The priority date for claims 9 and 14-19 of the '937 patent is April 23, 1985. Claim 9 of the '937 patent presents the compound famciclovir, identified as 2-amino-9-(4-acetoxy-3-acetoxymethylbut-1-yl)purine. Claim 14 of the '937 patent presents a method of treating viral infections in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 15 of the '937 patent presents a method of treating herpes virus infections in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 16 of the '937 patent presents a method of treating herpes simplex type 1 (HSV-1) in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 17 of the '937 patent presents a method of treating herpes simplex type 2 (HSV-2) in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 18 of the '937 patent presents a method of treating varicella zoster in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 19 of the '937 patent presents a pharmaceutical composition for treating viral infections which comprises famciclovir in combination with a pharmaceutically acceptable carrier.

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[2]The patent rights related to Famciclovir and Penciclovir were subsequently purchased by NPAG and NPC in August 2000.

The claimed compound famciclovir is a member of a class of compounds known as acyclic nucleosides. In 1977, a group from Burroughs Wellcome demonstrated that acyclovir (known by the chemical name 9-(2-hydroxyethoxymethyl)guanine), could selectively inhibit the herpes virus. Acyclovir is an acyclic nucleoside. Penciclovir is also an acyclic nucleoside. Acyclic nucleosides were known to have low bioavailability. Famciclovir is a prodrug– a pharmaceutical compound that does not have the desired activity (i.e., antiviral effects), but is converted in the human body into the active compound, in this case, penciclovir. The purpose of a prodrug is to increase the amount of active compound in the bloodstream after oral administration; that is, to increase the "bioavailability" of the active compound.

On June 20, 2008, Defendant sent Plaintiffs a Notice Letter informing them that it had filed Abbreviated New Drug Application ("ANDA") No. 78-679, including a Paragraph IV certification, seeking to market generic famciclovir tablets prior to the expiration of the '937 patent. Plaintiffs then filed a Complaint in this Court on July 31, 2008 alleging infringement of the '937 patent. Defendant has asserted numerous defenses, including invalidity of the patent due to obviousness and obviousness-type double patenting, and uneforceability of the patent due to inequitable conduct committed before the Patent & Trademark Office ("PTO").

II. STANDARD OF REVIEW

Summary judgment is granted only if all probative materials of record, viewed with all inferences in favor of the non-moving party, demonstrate that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. See FED. R. CIV. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986). "A party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion."

See Celotex Corp., 477 U.S. at 323. "This burden has two distinct components: an initial burden of production, which shifts to the nonmoving party if satisfied by the moving party; and an ultimate burden of persuasion, which always remains on the moving party." Id. at 330.

"In determining whether there are any issues of material fact, the Court must resolve all doubts as to the existence of a material fact against the moving party and draw all reasonable inferences - including issues of credibility - in favor of the nonmoving party." Newsome v. Admin. Office of the Courts of the State of N.J., 103 F. Supp.2d 807, 815 (D.N.J. 2000), aff'd, 51 Fed. Appx. 76 (3d Cir. 2002) (citing Watts v. Univ. of Del., 622 F.2d 47, 50 (D.N.J. 1980)).

While a court must draw reasonable inferences, the non-moving party "may not rest upon the mere allegations or denials of his pleading" to satisfy this burden, but must produce sufficient evidence to support a jury verdict in his favor. See FED. R. CIV. P. 56(e); see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). "[U]nsupported allegations in memorandum and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990). In addition, conclusory allegations are insufficient to establish genuine issues of fact. Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 902 (1990). The non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co., 475 U.S. at 586.

III. DISCUSSION

A. Infringement

Novartis has the burden of proving patent infringement by clear and convincing evidence. A determination of patent infringement involves two steps. "The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing

the properly construed claims to the device accused of infringing." Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc) (internal citations omitted), *aff'd*, 517 U.S. 370 (1996).

Here, there are disputes regarding the scope of the asserted patent claims, and Roxane does not contest that its generic famciclovir products are covered by Claims 9 and 14 through 19 of the '937 patent. However, Roxane has challenged the validity of the '937 Patent, and genuine issues of material fact as to the validity of the patent are in dispute. A party cannot infringe an invalid claim or the claims of an unenforceable patent. Since genuine issues of material fact exist as to the validity of the patent, Novartis' motion for summary judgment of infringement must be **denied**.

B. Obviousness

Roxane has challenged the validity of the '937 patent on the grounds that the famciclovir invention was obvious. Plaintiffs have moved for summary judgment that the '937 patent was non-obvious, and to dismiss this defense.[3]

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[3]In support of its motions for summary judgment, Plaintiffs argue that the '937 has already been fully litigated in a prior infringement action before this Court, wherein the jury rejected the obviousness and obviousness type double patenting defenses and found the '937 patent valid. See Jury Verdict Novartis Pharms. Corp. v. Teva Pharms. USA, Inc., No. 05-cv-1887, (D.N.J. Nov. 18, 2009), ECF No. 378. Plaintiffs also point out that following the jury verdict in the Teva litigation, this Court entered a consent judgment asserting that the '937 claims are valid. However, this Court agrees with Defendant that the Teva infringement litigation is not dispositive in the instant matter. Defendant was not a party to the Teva litigation. Since Defendant did not have a full and fair opportunity to litigate the issues in that case, the Teva litigation cannot have a preclusive effect on Defendant. See Innovad v. Microsoft Corp., 260 F.3d 1326, 1334 (Fed. Cir. 2001). Additionally, the Federal Circuit "has rejected *stare decisis* as generally inappropriate on the issue of validity of a patent." Mendenhall v. Cedarapids, Inc., 5 F.3d 1557, 1570 (Fed. Cir. 1993). "*Stare decisis* applies only if the underlying *factual findings* in the two cases are the same, not merely the *evidence*." Id.

To prevail on a defense of invalidity for obviousness, Defendant must demonstrate by clear and convincing evidence that:

> the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a).

"Patents are presumed to be valid." Proctor & Gamble Co. v. Teva Pharms., 566 F.3d 989, 994 (Fed. Cir. 2009) (citing Kao Corp. v. Unilever United States, Inc., 441 F.3d 963, 968 (Fed. Cir. 2006)). "A party seeking to invalidate a patent based on obviousness must demonstrate 'by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" Id. (citing Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1361 (Fed. Cir. 2007)). "Clear and convincing evidence places in the fact finder 'an abiding conviction that the truth of [the] factual contentions are highly probable.'" Id. (quoting Colorado v. New Mexico, 467 U.S. 310, 316 (1984)).

The Supreme Court has enumerated four factors to be considered by courts to assess whether an invention is obvious. Takeda v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (citing Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966)). The four factors are: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations, or "objective indicia of non-obviousness." Id.; see also KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 405 (2007). A court must make findings of fact and conclusions of law as to each of the four Graham factors.

In KSR International Co. v. Teleflex Inc., the Supreme Court cautioned against (1) a rigid application of the teaching, suggestion and motivation ("TSM") test, and (2) a rigid application of using an "obvious to try" analysis when there is pressure to solve a problem with "a finite number of identified, predictable solutions." 127 S. Ct. 1727, 741-42 (2007). Instead, the Court advocated a "common sense" approach to determining obviousness. See id. at 1741-43. Specifically, the Court explained that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining elements in the manner claimed." Id. at 1742. The Court reasoned that, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." Id. at 1740. Even in light of the new approach advocated by KSR, this Court must be cautious to avoid the use of hindsight when considering Defendant's obviousness argument. Thus,

> [i]n conducting an obviousness analysis, [a] factfinder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. This is because the genius of invention is often a combination of known elements that in hindsight seems preordained.

In re Omeprazole Patent Litig., 2007 U.S. Dist. LEXIS 39670, at *400-01 (S.D.N.Y. May 31, 2007) (citation omitted) (quoting KSR, 398 U.S. at 420); see also Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

In the context of chemical compounds, a Defendant challenging the validity of a patent must initially make a prima facie showing of obviousness. Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1345 (Fed. Cir. 2000); Kaufman Co. v. Lantech, Inc., 807 F.2d 970, 974-75 (Fed. Cir. 1986). Such a showing is made under the first Graham factors, as the challenging

party must (1) identify the prior art compound that a person of ordinary skill in the art would have chosen as the "lead compound" to select for further research, and (2) show that there is adequate support in the art for making the modifications necessary to arrive at the claimed compounds. Proctor & Gamble Co., 566 F.3d at 994-97; Takeda, 492 F.3d at 1356-57(explaining, after the Supreme Court's decision in KSR, that, "a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound in the prior art," and then the challenging party must identify "a reason that would have prompted a person of ordinary skill in the relevant field to combine [or modify] the elements in the way the claimed new invention does" to prove obviousness.). The "prior art as a whole" must be examined to determine whether a person of ordinary skill in the art would select a compound as a lead, and where there are many potential lead compounds, the selection of one particular compound is not an obvious choice. See Takeda Chemical 492 F.3d at 1363. All relevant properties of the compound must be considered in the obviousness calculus because "[w]hen claimed properties differ from the prior art, those differences, if unexpected and significant, may lead to nonobviousness." Eli Lilly & Co. v. Zenith Goldline, 471 F.3d 1369, 1378 (Fed. Cir. 2006).

If a party challenging a patent establishes a prima facie case of obviousness, then the patent-holder can rebut this showing by presenting objective evidence of non-obviousness. Yamanouchi, 231 F.3d at 1345. The "objective indicia" of non-obviousness, the fourth Graham factor, instructs courts to consider the circumstances surrounding the invention process including, but not limited to: (1) meeting a long-felt need, (2) the inventors' success despite the failure of others, (3) commercial success, (4) copying, (5) praise and recognition for the invention, (6) unexpected results, and (7) significant effort and serendipity. See Ruiz v. A.B. Chance Co., 234 F.3d 654, 660-62 (Fed. Cir.

2000); see also Proctor & Gamble, 566 F.3d at 994; Ortho-McNeil, 520 F.3d. 1358, 1364 (Fed. Cir. 2002).

Defendant argues that famciclovir would have been obvious based on the prior art available when the patent was filed in 1985. Specifically, Defendant relies on Krenitsky et. al., *Proc. Natl. Acad. Sci. USA,* 1984, 81, 3209 ("Krenitsky publication"), GB UK Patent Application 2,130,204 ("GB '204"), European Patent Application 085,424 ("EP '424"), Greek Application No. 80121 ("Greek Application"), and US Patent No. 4,798,833 ("833 Patent") to argue that it would have been obvious to one of ordinary skill in the art to select peniclovir for further development, and to apply the 6-deoxy and acetyl ester modifications to the peniclovir to improve oral bioavailability with the expectation that such modification would improve the bioavailability. Plaintiffs seek to rebut Defendant's argument by pointing to secondary considerations, such as unexpected results, as objective indicia demonstrating non-obviousness. Specifically, Plaintiffs argue that the famciclovir's low toxicity is an unexpected and surprising result that would not have been anticipated by a person of ordinary skill in the art. Not surprisingly, the parties' respective expert reports are conflicting as to whether or not famciclovir's toxicity levels are unexpected.

This Court finds that genuine issues of fact exist with respect to the scope, content and teaching of the prior art, differences between the prior art and the '937 patent, and secondary considerations such as unexpected properties. Accordingly, these factual disputes preclude a finding at the summary judgment stage and Plaintiffs' motion for summary judgment of non-obviousness is **denied**.

C. Obviousness Type Double Patenting

Roxane has also asserted obviousness-type double patenting as a defense. Roxane has moved for summary judgment that the '937 patent is invalid due to obviousness-type double patenting. Plaintiffs have moved for summary judgment dismissing this defense.

"Patents are presumed to be valid." Proctor & Gamble Co., 566 F.3d at 994 (citing Kao Corp. v. Unilever United States, Inc., 441 F.3d 963, 968 (Fed. Cir. 2006)). A party seeking to invalidate a patent based on obviousness-type double patenting must "prove double patenting by clear and convincing evidence, a heavy and unshifting burden." Symbol Tech., Inc. v. Opticon, Inc., 935 F.2d 1569, 1580 (Fed. Cir. 1991).

"Obviousness-type double patenting is a judicially created doctrine that prevents a patentee from extending the term of a patent by patenting an obvious variation on the original invention." Smith & Nephew, Inc. v. Arthrex, Inc., 2009 U.S. App. LEXIS 26268, *9 (Fed. Cir. Dec. 2, 2009) (citing Georgia-Pacific Corp. U.S. Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999)); see also General Foods Corp. v. Studiengesallschaft Kohle mbH, 972 F.2d 1272, 1282 (Fed. Cir. 1992) ("Double patenting is intended to prevent unjustified *extension* of protection."). "In general, the obviousness analysis applies to double patenting, except for three distinctions. First, statutory obviousness compares claimed subject matter to the prior art, while non-statutory double patenting compares *claims* in an earlier patent to *claims* in a later patent or application." P&G v. Teva Pharms. USA, Inc., 566 F.3d 989, 998 (2009) (emphasis added). "Second, double patenting does not require inquiry into a motivation to modify the prior art. Finally, double patenting does not require inquiry into objective criteria suggesting non-obviousness." Id. (internal citations omitted).

Under the obviousness-type double patenting doctrine, "a later patent claim is not patentable over an earlier patent claim if the later claim is anticipated by, or obvious in light of, the earlier claim." Smith & Nephew, 2009 U.S. App. LEXIS 26268 at *9 (citing Eli Lilly & Co. v. Barr Labs, Inc., 251 F.3d 955, 968 (Fed. Cir. 2001)). The test for obviousness-type double patenting "is whether the claims at issue would have been obvious to one of ordinary skill in the art over the subject matter of the claims of the first patent." Research Corp. Tech., Inc. V. Gensia Laboratories, Inc., 10 Fed. Appx. 856, 860 (Fed. Cir. 2001); see also General Foods, 972 F.2d at 1275-76. Patent claims are "definitions which must be read *as a whole*, [and] do not 'claim' or cover or protect all that their words may *disclose*." Id. at 1274; see also id. at 1281 (patent claims are examined "only to see what *has been patented*, the subject matter that *has been protected*, not for something one may find to be disclosed by reading them"). "The law of double patenting is concerned *only* with what patents *claim*... [and] therefore, involves an inquiry into what, if anything has been claimed twice." Id. at 1275. A disclosure in an earlier patent "cannot be used as though it were prior art." Id. at 1281. If the claim at issue is merely an obvious variation of the earlier patented claim, there is double patenting; but, if the challenged claim "defines *more* than an obvious variation, it is *patentably distinct*," and there is no double patenting. Id. at 1278.

Here, there is no dispute between the parties concerning the scope of claims 9 and 14 through 19 of the '937 patent.[4] Claims 9 and 14 through 19 of the '937 patent cover the compound

[4]As discussed in the Background section, the scope of the claims at issue are as follows: Claim 9 of the '937 patent presents the compound famciclovir, identified as 2-amino-9-(4-acetoxy-3-acetoxymethylbut-1-yl)purine. Claim 14 of the '937 patent presents a method of treating viral infections in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 15 of the '937 patent presents a method of treating herpes virus infections in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 16 of the '937 patent presents a method of treating herpes simplex type 1 (HSV-1) in a human or non-

famciclovir, methods of treatment using famciclovir, and a pharmaceutical composition of famciclovir.

Defendant contends that the '937 patent is invalid on the grounds of obviousness-type double patenting based on two-commonly owned patents, namely U.S. Patent Nos. 5,075,445 ("the '445 patent") and 4,942,166 ("the '166 patent").[5] Claim 1 of the '445 patent covers penciclovir in purified, crystalline form. The claims of the '166 patent cover crystalline monohydrate forms of penciclovir and penciclovir sodium salt, as well as a pharmaceutical composition and method of treatment using those compounds.

Defendant argues that the claims of the '445 and '166 patents cover the compound

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human animal using an effective, non-toxic amount of famciclovir. Claim 17 of the '937 patent presents a method of treating herpes simplex type 2 (HSV-2) in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 18 of the '937 patent presents a method of treating varicella zoster in a human or non-human animal using an effective, non-toxic amount of famciclovir. Claim 19 of the '937 patent presents a pharmaceutical composition for treating viral infections which comprises famciclovir in combination with a pharmaceutically acceptable carrier.

[5]Defendant originally based its obviousness-type double patenting on five commonly-owned patents, namely U.S. Patent Nos. 5,075,445 ("the '445 patent"), 6,579,981 ("the '981 patent"), 5,250,688 ("the '688 patent"), 5,684,153 ("the '153 patent"), and 6,388,074 ("the '074 patent"). Plaintiffs' expert calculated the patent expiration dates and found that four of these patents expired after the '937 patent, specifically '688 patent, '153 patent, '074 patent, and '981 patent. Defendant disputes the calculated expiration dates of the '074 and '981 patents and argue that they expire after the '937 patent. However, both parties agree that all four patents were issued *after* the '937 patent. To the extent Plaintiffs move for summary judgment of no obviousness-type double patenting with regard to these four patents, this Court finds there are genuine issues of material fact as to the expiration date, which precludes a finding of summary judgment. Additionally, in its motion for summary judgment, Defendant only relies on the '445 patent and U.S. Patent No. 4,942,166 ("the '166 patent"), which Defendant's expert introduced as an additional grounds for finding invalidity based on obviousness-type double patenting after receipt of Plaintiffs' expert's rebuttal report. Therefore, this Court will confine its obviousness-type double patenting analysis to the '445 and the '166 patents.

penciclovir, a pharmaceutical composition comprising penciclovir, and a method of treating viral infections comprising the administration of penciclovir, and that the '937 patent likewise is premised on the antiviral properties of penciclovir and the use of penciclovir's antiviral properties to treat viral infections. Defendant argues that the only difference between the famciclovir claims of the '937 patent and the penciclovir claims of the earlier '445 and '166 patents is that famciclovir has the 6-deoxy and diacetyl ester modifications. According to Defendant, the prior art demonstrated the following: penciclovir was an effective antiviral agent; acyclic guanine nucleosides, such as penciclovir, exhibited low bioavailability; the bioavailability of acyclic nucleosides could be improved through 6-deoxy and diacetyl ester modifications. Therefore, Defendant argues famciclovir is a mere obvious variation because it would have been obvious to one of ordinary skill in the art to use the 6-deoxy and diacetyl ester modifications to improve the bioavailability of penciclovir.

Defendant also argues that the only difference between the methods of treatment claims in the '937 patent and that of the '445 and '166 patents is that in the former the famciclovir is administered and converted *in vivo* to penciclovir, while in the latter the penciclovir is administered directly. These differences are patentably indistinct, according to Defendant, since both methods of treatment are based on the antiviral activity of penciclovir.

Plaintiffs argue that the chemical compound needs to be considered as a whole, and therefore Defendant's focus on only one property of famciclovir, namely its improved bioavailability, is misplaced. Plaintiffs also argue that the improved bioavailability was neither obvious nor expected, and the factual assertions forming the basis for Defendant's motion are incorrect, or, at the very least, in genuine dispute. Plaintiffs challenge Defendant's reliance on the prior art references, arguing the

prior art does not disclose that ester modifications of 6-deoxy compounds would improve bioavailability, and that the patent examiner allowed the '937 patent only after considering the penciclovir prior art (including the application for the '445 patent) as well as GB '204 (disclosing ester modifications of 6-deoxy acyclic nucleoside compounds). According to Plaintiffs, the process through which famciclovir was invented, which included numerous failed attempts involving ester derivatives and 6-deoxy penciclovir, demonstrates that the improved bioavailability was not expected and that famciclovir is not a mere obvious variation of penciclovir. Finally, Plaintiffs point to the failed efforts of others in the field working with penciclovir and the experiences with acyclovir as proof that the improved bioavailability of famciclovir was unexpected.

This Court finds that there are genuine issues of material fact in dispute as to whether or not the 6-deoxy and diacetyl ester modifications are mere obvious variations of the claims in the '445 and '166 patents, or whether famciclovir is patentably distinct from penciclovir. Therefore, Defendant's motion for summary judgment of obviousness-type double patenting, and Plaintiffs' motion for summary judgment of no obviousness-type double patenting are **denied**.

D. Inequitable Conduct

Plaintiffs move for summary judgment of no inequitable conduct. Defendant moves for summary judgment of inequitable conduct. Plaintiffs also filed a cross motion to preclude Defendant's new inequitable conduct contention and evidence, or, alternatively, to strike those portions of Defendant's motion for summary judgment.

1. Cross Motion to Preclude, or, Alternatively, to Strike

"Inequitable conduct, while a broader concept than fraud, must be pled with particularity

under Rule 9(b)." Exergen Corp. v. Wal-Mart Stores Inc., 575 F.3d 1312, 1326 (Fed. Cir. 2009)(internal citations omitted). Whether inequitable conduct has been adequately pled is a matter of Federal Circuit law. See id. "A pleading that simply avers the substantive elements of inequitable conduct, without setting forth the particularized factual bases for the allegation, does not satisfy Rule 9(b)." Id. at 1326-27. "[I]n pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." Id. at 1327. Additionally, the pleading "must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Id. at 1328-29. This particularity is required "lest inequitable conduct devolve into a magic incantation to be asserted against every patentee and its allegation established upon a mere showing that art or information having some degree of materiality was not disclosed." Id. at 1331 (internal citations omitted). When a defendant fails to plead inequitable conduct with the particularity required "to give notice to the other party of the facts on which the defense is premised," the defense may be "*properly dismissed by the district court*." Central Admixture Pharmacy Services, Inc.v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1357 (Fed. Cir. 2007) (emphasis added); see also Exergen, 575 F.3d at 1325-32 (affirming district court's ruling that defendant was not allowed to add inequitable conduct as an affirmative defense because the allegations of inequitable conduct were deficient due to lack of particularity).

Under Fed. R. Civ. P. 12(f), "[t]he court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). The court

may do so on its own or on a motion made by a party. Id.

a. European Patent 085,424 ("EP '424")

Plaintiffs assert that Defendant should be precluded from arguing that Plaintiffs intentionally withheld European Patent 085,424 ("EP '424") from the patent examiner. Plaintiffs argue Defendant's EP '424 inequitable conduct defense is based on allegations that were not previously disclosed in any of Defendant's pleadings, expert reports or discovery responses, and was improperly raised for the first time in Defendant's motion for summary judgment.[6] In support of their argument, Plaintiffs note the following: Defendant, in its answer and counterclaim, alleged that the '937 patent was unenforceable due to inequitable conduct resulting from the failure of the '937 patent applicants to disclose six allegedly material prior art references, none of which was EP '424; Defendant did not include EP '424 in its response to interrogatories on inequitable conduct contention or its supplemental response to the interrogatories; Defendant did not amend its pleadings to add its EP '424 inequitable conduct allegations; and none of the Defendant's expert reports reference EP '424 in relation to the inequitable conduct allegations.

In response, Defendant contends that the Plaintiff was on notice of the EP '424 inequitable conduct defense based on the parties' experts reports and depositions and the deposition of the inventor Dr. Harnden, all of which demonstrated Defendant's intent to use EP '424 in its inequitable conduct defense. In support of its argument, Defendant cites to a portion of its expert's report discussing the materiality of EP '424 and notes that the expert report not only provides an extensive discussion of EP '424's materiality but also references EP '424 twenty-three times. Defendant argues

[6]Defendant raised several theories of inequitable conduct in its motion for summary judgement, which are discussed in detail below.

that since it always advanced an inequitable conduct defense, the extensive discovery regarding EP '424 should have been sufficient to alert Plaintiff to Defendant's intent to use EP '424 as part of its inequitable conduct theory.

Defendant's arguments ignore not only the requirement that allegations of inequitable conduct be pled with particularity, but also the fact that inequitable conduct is a wholly different defense than patent invalidity based on obviousness. It is apparent that EP '424 was a focus of the discovery and expert reports with regard to obviousness. However, obviousness and inequitable conduct are not the same defense as the latter includes elements of culpability and purposeful deceit while the former does not. The fact that Plaintiffs knew EP '424 would be offered in support of the obviousness defense does not relieve Defendant of its duty to plead inequitable conduct with particularity so as to provide Plaintiffs with sufficient notice as to the factual basis for the defense. For example, in Exergen, the party challenging the patent plead inequitable conduct as an affirmative defense; the challenger's pleadings identified specific patents that were not disclosed to the PTO, stated how the patent holder knew of these patents, alleged the materiality of the non-disclosed patents and the intent to deceive the PTO, and identified contradictory arguments made by the patent holder in the prosecution of the patent. Exergen Corp., 575 F.3d at 1325. Nonetheless, the Federal Circuit affirmed the district court's decision preventing the challenger from adding inequitable conduct as an affirmative defense because the proposed pleadings lacked the requisite particularity. Exergen Corp., 575 F.3d at 1325,1331. Here, with regard to Defendant's theory of inequitable conduct based on Plaintiffs' failure to disclose EP '424, Defendant failed to identify the "specific who, what, when, where, and how of the material representation or omission committed before the PTO" as is required. See Exergen Corp., 575 F.3d at 1327.

Accordingly, Plaintiffs' motion to preclude Defendant's theory of inequitable conduct based on the failure to disclose the EP '424 reference is **granted**.

b. Schaeffer Compound

Plaintiffs argue that Defendant, in its summary judgment motion, introduced new evidence in support of a previously disclosed theory of inequitable conduct; the previously disclosed theory was that the '937 patent applicants misled the patent examiner by incorrectly arguing that the prior art penciclovir has no antiviral activity. This new evidence concerns arguments the '937 patent applicants made regarding a compound (referred to in Defendant's motion for summary judgment as the "Schaeffer compound" and in the '937 patent file history as "compound F") with a surprisingly unfavorable anti-viral activity as compared to penciclovir. Plaintiffs argue that not only was this evidence not disclosed in any of Defendant's pleadings, discovery responses, or expert reports, but also that the previously disclosed evidence in support of this theory concerned different arguments made by the Plaintiffs, pointing out that methylene compounds compared unfavorably to their ether analogs with respect to antiviral activity.

Defendant counters it adequately disclosed this theory of inequitable conduct in its original interrogatory responses, and that the Schaeffer compound can not be categorized as "new evidence." There does not seem to be much dispute as to whether Defendant plead the theory of inequitable conduct based on Plaintiff's misrepresentation as to penciclovir's antiviral activity with the required particularity; Defendant plainly identified its position that Plaintiffs intentionally, and repeatedly, made false and misleading statements regarding penciclovir's antiviral activity and whether compounds having methylene moiety should be expected to work. Defendant put the Plaintiffs on notice as to the who, what, where, when and how of the material misrepresentation, and the

statements regarding the Schaeffer compound fall squarely within the facts disclosed by Roxanne in support of its theory of inequitable conduct.

Nonetheless, Plaintiffs argue that Defendant should be precluded from relying on the Schaeffer compound in support of Defendant's theory of inequitable conduct because this represents 'new evidence,' and since Defendant did not supplement its interrogatories, Defendant violated Fed. R. Civ. P. 26(e)(1). Fed. R. Civ. P. 26(e)(1) provides in relevant part, "A party who has made a disclosure under Rule 26(a)--or who has responded to an interrogatory, request for production, or request for admission--must supplement or correct its disclosure or response ... in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing."

Plaintiffs argue Defendant failed to supplement its interrogatories and Plaintiffs only became aware of Defendant's intention to rely on the Schaeffer compound in Defendant's motion for summary judgment. Therefore, Plaintiffs argue, Defendant should be precluded from relying on the Schaeffer compound based on Fed. R. Civ. P. 37, which provides in relevant part "[i]f a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless."

Defendant argues that since it disclosed the factual basis for its claim of inequitable conduct, its interrogatory response was not incomplete and, therefore, there was no violation of Fed. R. Civ. P. 26(e). Defendant also argues that since Plaintiffs' witnesses were questioned on the statements about the Schaeffer compound during depositions, and these statements were referenced in response

to expert reports, Plaintiffs were made aware of the Schaeffer compound through the course of discovery, making any failure to supplement interrogatories harmless. See Accenture Global Servs. GMBH v. Guidewire Software, Inc., 691 F. Supp. 2d 577 (D. Del. 2010).

This Court agrees with Defendant that it properly disclosed the facts on which it was relying in support of its inequitable conduct defense, the Schaeffer compound does not represent "new evidence," and there was no violation of Fed. R. Civ. P. 26(e). Accordingly, Plaintiffs' motion to preclude Defendant from relying on the Schaeffer compound is **denied**.

2. Motions for Summary Judgment

It is well settled that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [Patent] Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." McKesson Info. Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897, 913 (Fed. Cir. 2007); see also M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc., 439 F.3d 1335, 1339 (Fed. Cir. 2006) ("Patent applicants and those substantively involved in the preparation or prosecution of a patent application owe a 'duty of candor and good faith' to the PTO."). A breach of this duty constitutes inequitable conduct, which subjects any resulting patent to nullification. To establish inequitable conduct, a party must show that the patent applicant, "with intent to mislead or deceive the examiner, fail[ed] to disclose material information or submit[ed] material false information to the PTO during prosecution." McKesson, 487 F.3d at 913. Inequitable conduct, therefore, has two elements: 1) materiality and 2) intent.

Information is material "when a reasonable examiner would consider it important in deciding

whether to allow the application to issue as a patent." Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1297 (Fed. Cir. 2008). The Federal Circuit has explained that the issue of "materiality" does not center on whether the withheld information would have rendered the claims invalid; rather, materiality relates to whether it is a matter "within a reasonable examiner's realm of consideration." Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1421 (Fed. Cir. 1989). "Information concealed from the PTO may be material even though it would not invalidate the patent." Li Second Family Ltd. v. Toshiba Corp., 231 F.3d 1373, 1380 (Fed. Cir. 2000). However, an otherwise material reference is not material if it is merely cumulative to, or less relevant than, information already considered by the examiner. See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1577 (Fed. Cir. 1996); FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987).

To determine whether there is intent to deceive the examiner, courts look at all the facts surrounding an applicant's overall conduct, including evidence of good faith, and may infer culpability because "[i]ntent rarely can be, and need not be, proven by direct evidence." Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1364 (Fed. Cir. 2007); see also M. Eagles, 439 F.3d at 1341. In order to prove intent, more than an omission of material information is necessary; "clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required." Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990). "An inference of intent to deceive is generally appropriate, however, when (1) highly material information is withheld; (2) the applicant knew of the information [and] ... knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding." Praxair Inc. v. ATMI, Inc., 543 F.3d 1306, 1313-14 (internal citations omitted).

Materiality and intent are separate elements of inequitable conduct, and must each be proven by clear and convincing evidence for a patent to be rendered unenforceable. Cargill, Inc., 476 F.3d at 1364. "Once threshold findings of materiality and intent are established, the court must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred." Molins Plc v. Textron, 48 F.3d 1172, 1178 (Fed. Cir. 1995) (citation omitted). "In light of all the circumstances, an equitable judgment must be made concerning whether the applicant's conduct is so culpable that the patent should not be enforced." Id. (citing LaBounty Mfg., Inc. v. Int'l Trade Comm'n, 958 F.2d 1066, 1070 (Fed. Cir. 1992). The showing of intent can be proportionally less when balanced against high materiality. N.V. Akzo v. E.I. DuPont de Nemours, 810 F.2d 1148, 1153 (Fed. Cir. 1987). Similarly, the showing of intent must be proportionally greater when balanced against low materiality. Id.

"Although it is not impermissible to grant summary judgment of inequitable conduct, [the Federal Circuit] 'urges caution' in making an inequitable conduct determination at the summary judgment stage." M. Eagles, 439 F.3d at 1340.

Defendant offers three theories of inequitable conduct: (1) applicants withheld material Wellcome Publications, which disclosed the 6-deoxy modification of acyclovir, from the PTO; (2) applicants' representations concerning the "surprising and unexpected" antiviral activity of penciclovir were false and misleading; and (3) applicants made false and misleading arguments concerning the antiviral activity of penciclovir, particularly in comparison to methylene moiety, and withheld material references that refuted those arguments.

In response to each of Defendant's theories of inequitable conduct, Plaintiffs argue that neither the elements of materiality nor intent to deceive are present. Plaintiffs argue that the

withheld publications were not material, but were merely cumulative of other information presented to, and considered by, the PTO. Plaintiffs also argue Defendant mischaracterized the arguments made to the PTO by the patent applicants, and challenge Defendant's characterizations of Plaintiffs' statements to the PTO as 'false' and 'misleading.' Finally, Plaintiffs argue that they lacked the intent to deceive the PTO.

This Court finds there are genuine issues of material fact with regard to the materiality of the withheld information and alleged misrepresentations. Likewise, this Court finds that there are genuine issues of material fact with regard to whether Plaintiffs possessed the requisite intent to deceive the PTO. Accordingly, these factual disputes preclude a finding at the summary judgment stage, and Plaintiffs' motion for summary judgment of no inequitable conduct and Defendant's motion for summary judgment of inequitable conduct are **denied**.

IV. CONCLUSION

In accordance with the foregoing, Plaintiffs' motions for summary judgment of infringement, non-obviousness and no obviousness-type double patenting, and no inequitable conduct are **denied**; Defendant's motions for summary judgment of obviousness-type double patenting and inequitable conduct are **denied**; Plaintiffs' cross motion to preclude new inequitable conduct content and evidence is **granted in part and denied in part**. An appropriate Order accompanies this Opinion.

S/Dennis M. Cavanaugh

Dennis M. Cavanaugh, U.S.D.J.

Date: March 31, 2011

Orig.: Clerk
cc: Counsel of Record
The Honorable Joseph A. Dickson, U.S.M.J.
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